

May 24, 2001

Ms. Caroline Garber  
Chief, Environmental Studies Section  
Bureau of Air Management  
Wisconsin Department of Natural Resources  
101 South Webster Street  
Madison, WI 53707

Dear Ms. Garber:

At the April public meeting on NR 445, you and your staff presented the Department's findings on diesel exhaust particulate emissions and distributed an Issues Paper outlining the proposed approach to regulate diesel emissions under NR 445. The Engine Manufacturers Association (EMA) previously submitted comments and information on listing diesel exhaust particulates and has also had the opportunity to meet with you on these issues. EMA believes that the emissions from stationary diesel engines in Wisconsin continue to be low and that there is no health-based justification for removing the fossil fuel exemption for diesel-fueled compression-ignition engines currently in effect under NR 445.

EMA would like to provide additional comments on two issues brought up at the April public meeting: the use of the risk range published by the US EPA in the Diesel Health Assessment Document and the inclusion of portable equipment within the regulatory scope of NR 445.

**1. The DNR has misinterpreted and misused EPA's risk range for diesel particulate matter in the analysis of diesel health effects and the April 2001 Issues Paper on Diesel PM. The analysis using the EPA risk range should be removed from the paper.**

The US EPA has readily admitted, and EPA's independent technical review committee, the Clean Air Scientific Advisory Committee (CASAC), fully agrees that the existing epidemiology database on diesel emissions and lung cancer are insufficient to determine a unit risk factor. In the Diesel Health Assessment Document, CASAC Comment Review Draft dated October 2000, EPA indicates:

“For DE (diesel exhaust particulate) the exposure response data in rat studies are not deemed appropriate for the estimation of human risk. Exposure response data in available human epidemiology studies are considered too uncertain to derive a confident quantitative estimate of cancer unit risk. Therefore, EPA has chosen not to derive a quantitative estimate of cancer unit risk.” EPA Diesel Health Assessment Document, Executive Summary, Section 1.63.

EPA then goes on to perform a simple analysis of environmental cancer risk based upon general epidemiology principles and differences between occupational and environmental exposures. EPA indicates that this analysis was performed to provide an assessment as to whether there is any health effects that may be of regulatory concern. In Sections 8.4 and 9.5.2 of the HAD, EPA derives and reports a potential lifetime risk range of  $10^{-5}$  to  $10^{-3}$ . Regarding this risk range, EPA says:

“It should be pointed out that these analyses are subject to considerable uncertainties, particularly the lack of actual exposure information and the underlying assumption that cancer risk is linearly proportional to cumulative exposure . . . These findings are general indicators of the potential significance of lung cancer hazard, and should not be viewed as a definitive quantitative characterization of risk.” EPA Diesel Health Assessment Document, Chapter 9, Section 9.52, Emphasis Added.

During the CASAC review meeting on the HAD in October 2000, Dr. Bill Farland, Director of EPA’s National Center for Environmental Assessment, who is responsible for the HAD, confirmed that the reported risk range is not a unit risk factor and should not be used as such. Further, the risk range in question was derived from basic epidemiological principles and refers to an upper bound lifetime risk at environmental levels of exposure.

In their review of the document, CASAC expressed many concerns about the derivation of the risk range as well as its potential misapplication. In their formal written comments to EPA, CASAC indicated:

“(EPA) staff made clear its intent that its listing of the values (risk range) was not to be interpreted as the Agency’s endorsement of their use as unit risk values. There were mixed views among both the Committee and Consultants regarding the appropriateness of including the range; however, there was general agreement that, despite the Agency disclaimers, the publication of the range would likely be cited as an endorsement of the values as unit risks for estimating cancer deaths. Consensus was already established that no unit risk values could be calculated with sufficient confidence to be presented in the document as an Agency position”

“The Panel generally, but not unanimously agrees that the inclusion of the range of values would not prevent a recommendation for closure on the document,

pending the accompanying inclusion of satisfactory caveats and disclaimers. Although agreement was not reached on specific language, it was agreed that the disclaimers would include clear statements that 1) the values were attended by considerable uncertainty; 2) that the inclusion in the document did not constitute Agency endorsement of their validity as unit risk values; 3) that the values are not proposed as useful for estimating numbers of cancer deaths; and 4) that the range of potential risk from environmental exposures was very broad and included at its lower bound the possibility of zero risk.” US EPA Science Advisory Board, Review of EPA’s Health Assessment Document for Diesel Exhaust, EPA-SAB-CASAC-01-003, December 2000 Section 3.8.

It is clear from both EPA and CASAC comments, as well as the methodology used to derive the range, that the potential lifetime risk ranges reported in the HAD are not unit risk factors. Additionally, the risk range is reported as a lifetime risk and is not associated with any specific exposure levels. That is, whereas unit risk factors are reported on the basis of exposure to a specific ambient concentration, e.g., micrograms per cubic meter of substance, the risk range reported in the HAD does not have any units associated with it.

The DNR Issues Paper on Diesel Exhaust Particulate Emissions and NR445 dated April 2001, incorrectly and inappropriately uses the risk range reported in the HAD as unit risk factors. Although acknowledging CASAC concerns and caveats regarding use of the risk range on Page 4 of the Issues Paper, DNR staff incorporates the EPA risk ranges into their Analysis of Diesel Exhaust Emissions in Appendix 1. Staff clearly uses the EPA range, along with unit risk factors by the California Air Resources Board, to calculate Impact Levels and cancer risks to the population in both Table 1 and Table 2A of the document. To do so, staff used the EPA risk range as upper and lower bound unit risk factors and assumed that the risks reported by EPA were based on exposure to 1 microgram per cubic meter of diesel particulate matter.

The Issues Paper incorrectly uses the risk range reported in the HAD in precisely the manner that EPA and CASAC indicated should not be done. The analyses are based upon a faulty interpretation of the EPA risk range, are in direct contradiction to both EPA and CASAC direction on this matter, and should be removed from the analysis. Indeed, unless those risk ranges, impact levels, and cancer risk calculations are removed, any DNR regulatory efforts stemming from these ranges and calculations will be improper, arbitrary, and capricious and will not withstand subsequent judicial scrutiny.

Additionally, as EMA has indicated in previous comments submitted to you, the analyses using the unit risk factors developed by California are also invalid and should be removed. The California unit risk ranges are based upon the very same studies that both EPA and CASAC have clearly indicated are inadequate to derive unit risk factors. As indicated by CASAC:

“The Committee continues to agree with Staff’s decision not to adopt a unit risk value. It was agreed that no single existing data set, or combination of existing data sets, allows for the calculation of and estimate of unit risk with acceptable confidence. It was felt unlikely that continued evaluation of data sets from past epidemiological studies will resolve uncertainties to a satisfactory degree, due primarily to the lack of exposure information. There were mixed reviews regarding the likelihood that future studies will provide an acceptable unit risk value applicable to environmental exposure.” US EPA Science Advisory Board, Review of EPA’s Health Assessment Document for Diesel Exhaust, EPA-SAB-CASAC-01-003, December 2000 Section 3.8.

Based on the above scientific opinions of the leading independent experts on this subject, DNR should remove any quantitative assessments of cancer risk attributable to diesel emissions from the Issues Paper.

**2. NR 445 is not applicable to portable equipment and engines since the Clean Air Act defines portable equipment as mobile sources and preempts states from imposing additional or alternative emissions standards.**

The third recommendation in the April Issues Paper indicates that:

“Emissions from stationary and portable diesel-fueled engines should be regulated as a source category in NR 445.”

Section 209 of the Clean Air Act, 42 USC § 7543, preempts states and their political subdivisions from adopting standards or any other requirements relating to the control of emissions from mobile sources. Section 209(e) pertaining to Nonroad Engines and vehicles specifically provides that:

“No state or any political subdivision thereof shall adopt or attempt to enforce any standard or other requirement relating to the control of emissions from either of the following new nonroad engines or nonroad vehicles subject to regulations under this Act - New engines used in construction equipment or vehicles or used in farm equipment or vehicles and which are smaller than 175 horsepower.”

Subsection (2) of Section 209(e) extends this preemption to all other new and non-new nonroad engines or vehicles, and provides that only California may apply to the US EPA for authorization to adopt standards or controls governing such engines, equipment, or vehicles. Other states may thereafter adopt standards identical to California’s after notice to EPA.

Significant in this regard is the fact that portable engines and equipment are a subset of the federally-preempted nonroad engines and vehicles. This is made explicit under controlling federal regulations. More specifically, pursuant to 40 CFR Part 89,

Control of Emissions from New and In-use Nonroad Engines, “Nonroad Engines” are defined as any internal combustion engine “that is self propelled, is intended to be propelled while performing its function, or that, by itself or in or on a piece of equipment is portable or transportable, meaning designed to be and capable of being carried or moved from one location to another.” The regulation further states that an internal combustion engine is not a nonroad engine if “the engine remains or will remain at a location for more than 12 consecutive months or a shorter period of time for an engine located at a seasonal source.”

Accordingly, a compression ignition engine in portable equipment is considered a nonroad engine under this definition if it does not remain in the same location for more than twelve months. Therefore, since portable engines and equipment meet the definition of nonroad engines, they are covered by federal emissions standards and the states are preempted from regulating these engines under the express preemption provisions of Section 209 of the Clean Air Act. As a result, the DNR is not authorized to regulate portable equipment. To the contrary, the DNR is expressly preempted from doing so under controlling federal law.

Although Section 209 of the Clean Air Act precludes Wisconsin from adopting standards or regulatory programs for non-road engines, equipment (including portable equipment), or vehicles, nothing in Section 209 precludes Wisconsin from establishing reasonable standards for stationary sources. Therefore, NR 445 provisions should only apply to equipment or engines from stationary sources, i.e., equipment that remains in one location longer than 12 consecutive months.

Please take the above comments into consideration when revising the Issues Paper and in drafting changes to NR 445. As always, EMA would be happy to respond to any questions that you may have.

Sincerely,

Joseph L. Suchecki  
Director, Public Affairs